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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,795

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Kohzo Ito

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EXAMINER

WRIGHT, SONYA N

ART UNIT

PAPER NUMBER

1796

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,795	<b>Applicant(s)</b> ITO ET AL.	
	<b>Examiner</b> SONYA WRIGHT	<b>Art Unit</b> 1796	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-5 are pending in this application. Claims 6-8 have been cancelled by Applicant's amendment filed November 6, 2009.

Applicant's response to the restriction requirement mailed July 1, 2009, is compliant in view of the complete listing of all claims with status identifiers in Applicant's amendment filed November 6, 2009.

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-5 in the reply filed on July 13, 2009 is acknowledged.

### ***Claim Objections***

Claim 3 is objected to because of the following informalities: Claim 3 contains "TEMPO" in parenthesis. Since Applicant has provided the full name of TEMPO, 2,2,6,6-tetramethyl-1-piperidinyloxy radical, in claim 3, the term "TEMPO" is redundant and not needed. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Rejection over Watanabe et al.

Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Watanabe et al., Journal of Artificial Organs 3:136-142, 2000.

For a teaching of the instant invention, see Watanabe et al., page 137, "Materials and methods, Preparation of ester-terminated polyrotaxanes." Watanabe et al. teach a method wherein terminal hydroxyl groups in PEG are subjected to succinylation. Then the succinylated PEG is activated. Next the activated PEG is aminated. The endcapping reaction of the polypseudorotaxane included the use of benzyloxycarbonyl-L-phenylalanine succinimide ester. Z-L-Phe was used as a terminal end-group to prevent dissociation of the cyclodextrin molecules.

Rejection over Platzek et al.

Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,113,880, Platzek et al.

For a teaching of the instant invention, see Platzek et al., columns 21 and 22, Example 2. In Example 2, a polyrotaxane that consists of alpha-cyclodextrin and the PEG-bisamide derivative of O,O'-bis(glycyl)-PEG and N-alpha-benzyloxycarbonyl-phenylalanine was prepared. O,O'-bis(glycyl)-PEG was added to a solution of alpha-cyclodextrin. A precipitate was formed. N-alpha-benzyloxycarbonyl-phenylalanine-N-hydroxysuccinimide ester, triethylamine, and the alpha-cyclodextrin-pseudopolyrotaxane were dissolved in DMSO and later mixed with diethyl ether. A polyrotaxane precipitate resulted.

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Rejection over JP 09-301893 (Applicant's translation from the IDS filed February 5, 2008.)

Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 09-301893.

JP '893 teaches the instant invention in the working examples in [0011]-[0015]. In the examples a triblock copolymer consisting of PEG and PPG was used. Succinic anhydride was added to the copolymer, and a carboxyl group was introduced into the block copolymer. Dicyclohexylcarbodiimide was also used . An N-succinimid ester was prepared. The polyrotaxane was prepared, and 2-naphthylamine and 8-disulfonic acid mono-potassium salt were introduced into both ends of a clathrate compound as bulky end groups, to prevent the dissociation of the cyclodextrine molecules.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Rejection over Watanabe et al. in view of de Nooy et al.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over as Watanabe et al., as applied to claims 1, 2, 4, and 5 above, and further in view of de Nooy et al., Tetrahedron 51(29), pp.8023-8032.

The instant claims are drawn to polyrotaxanes and a method for producing the same. Watanabe et al. teach a method wherein terminal hydroxyl groups in PEG are subjected to succinylation. Then the succinylated PEG is activated. Next the activated PEG is aminated. The endcapping reaction of the polypseudorotaxane included the use of benzyloxycarbonyl-L-phenylalanine succinimide ester. Z-L-Phe was used as a terminal end-group to prevent dissociation of the cyclodextrin molecules.

Watanabe et al. do not teach the use of 2,2,6,6-tetramethyl-1-piperidinyloxy radical (TEMPO). However, de Nooy et al. teach the use of TEMPO in alcohol oxidation reactions. One of ordinary skill in the art would be motivated to combine de Nooy et al. with Watanabe et al. because it is well established that TEMPO can be

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applied as a mediator for the oxidation of alcohols and because the method of de Nooy uses mild conditions, making de Nooy's method applicable to a variety of alcoholic substrates. See de Nooy, page 8023, first paragraph of the introduction.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SONYA WRIGHT whose telephone number is (571)272-5857. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ling-Siu Choi/  
Primary Examiner, Art Unit 1796

/SONYA WRIGHT/  
Examiner, Art Unit 1796

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